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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,292	01/27/2006	Nicoletta Almirante	026220-00073	1937

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ARENT FOX LLP  
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EXAMINER
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KOSACK, JOSEPH R

ART UNIT	PAPER NUMBER
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1626

NOTIFICATION DATE	DELIVERY MODE
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11/18/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DCIPDocket@arentfox.com  
IPMatters@arentfox.com  
Patent\_Mail@arentfox.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/566,292	<b>Applicant(s)</b> ALMIRANTE ET AL.	
	<b>Examiner</b> Joseph R. Kosack	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-21 is/are pending in the application.
- 4a) Of the above claim(s) 3, 16, 17 and 19-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5-15 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/27/06, 3/30/06, 6/6/06</u>                                  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 1-3 and 5-21 are pending in the instant application.

#### ***Election/Restrictions***

It is noted that claim 4 was cancelled before the mailing of the restriction requirement and that claim should not have been listed as pending. The list of pending claims and Groups in the requirement are amended accordingly.

Applicant's election without traverse of Group I (claims 1-3 (in part), 5-14 (in part), 15-17, and 18-21 (in part)) along with an election of species in the reply filed on August 7, 2008 is acknowledged.

As the elected species has been found to be unpatentable, the search has been limited to the elected species. As the Applicant submits that only claims 1, 2, 5-15, and 18 read on the elected species, claims 3, 16, 17, and 19-21 have not been currently searched and are withdrawn by the Examiner under 37 CFR 1.142(b) as being drawn to a non-elected invention.

#### ***Priority***

The claim to priority as a 371 filing of PCT/EP04/51550 filed July 20, 2004, which claims benefit of EP 03102379.9 filed July 31, 2003 is acknowledged in the instant application.

#### ***Information Disclosure Statement***

The Information Disclosure Statements filed on January 27, March 30, and June 06, 2006 have been considered by the Examiner.

#### ***Claim Rejections - 35 USC § 103***

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 5-15, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over McIntyre et al. (*Pharmacol. Ther.*, 1997, 181-194) in view of Del Soldato (WO 00/61537).

The instant claims are drawn to nitrooxy derivatives of Angiotensin II receptor blocker drugs. The species searched is a derivative of the drug losartan.

McIntyre et al. teach the drug losartan. See the whole document, specifically page 182 for the structure of losartan.

McIntyre et al. do not teach attaching a nitrooxy tether to the drug as instantly claimed.

Del Soldato teaches that the addition of a nitrooxy tether to drugs such as losartan remove side effects to patients affected by oxidative stress and/or endothelial dysfunctions or to the elderly in general. See pages 6-13. The exact tether that is used in the species is shown in Example 10 on page 84.

Therefore, one of ordinary skill in the art would be motivated to take losartan, which is discussed at length by McIntyre et al. and attach the nitrooxy tether as shown by Del Soldato and described as capable of function with losartan, with a reasonable expectation of success. The motivation for making the change is that the addition of a nitrooxy tether to drugs such as losartan remove side effects to patients affected by oxidative stress and/or endothelial dysfunctions, or to the elderly in general.

Thus, the claims are *prima facie* obvious over the prior art.

### **Conclusion**

Claims 1, 2, 5-15, and 18 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph R. Kosack whose telephone number is (571)272-5575. The examiner can normally be reached on M-Th 6:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Joseph R Kosack/  
Examiner, Art Unit 1626

/REI-TSANG SHIAO /  
Primary Examiner, Art Unit 1626